

REMARKS

Claims 1-46 are pending in the above-identified patent application. Claims 1-10, 12-22, and 38-46 are withdrawn from consideration pursuant to a Restriction Requirement that has been made final. Accordingly, claims 11, 24-25, and 27-37 remain for consideration.

Claims 25-37 were rejected under the second paragraph of 35 U.S.C. § 112 as indefinite for the recitation of the phrase “comprising at least.”

Claims 11, 24-32, and 34-37 were rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious, over U.S. Patent Application Publication No. 2004/0204433 by Imamura et al. (“Imamura et al. ‘433”).

Reexamination of the application as amended, reconsideration of the rejections, and allowance of the claims remaining for consideration are respectfully requested.

The shortened statutory period for response to this Office Action expires on April 28, 2008. Accordingly, this response is being filed in a timely manner. The Office Action stated: “A shortened statutory period for reply is set to expire 1 month or thirty (30) days, whichever is longer, from the mailing date of this communication.” However, the undersigned spoke to Examiner Choi and he indicated that the 1-month indication for the response deadline was a typographical error. He agreed that the proper shortened statutory period for a response to a first Office Action on the merits should be three months, and this response is being filed in accordance with that correct shortened statutory period.

I. AMENDMENTS TO THE CLAIMS

Entry of the amendments to the claims is respectfully requested. As detailed below, the amendments introduce no new matter.

Claims 11 and 24 are amended to make these claims independent. Claim 25 is amended to delete the phrase “at least” from the claim. These amendments do not significantly alter the scope of the claim and do not introduce new matter.

This response is being filed in accordance with recently revised 37 C.F.R. § 1.121, as set forth in 68 F.R. 38611 (June 30, 2003). If the amendment is considered to be not in compliance with recently revised 37 C.F.R. § 1.121, the Examiner is respectfully requested to contact the undersigned at his earliest possible convenience.

II. THE RESTRICTION REQUIREMENT

In the response to the Restriction Requirement, Applicants elected the invention of Group II, claims 11 and 24-37, with traverse. The Restriction Requirement has been made final. Applicant acknowledges the finality of the Restriction Requirement, but preserves the right to petition for reconsideration of the Restriction Requirement under 37 C.F.R. §§ 1.144 and 1.181.

III. THE REJECTIONS OF CLAIMS 25-37 UNDER THE SECOND PARAGRAPH OF 35 U.S.C. § 112

Claims 25-37 were rejected under the second paragraph of 35 U.S.C. § 112 as indefinite for the recitation of the phrase “comprising at least.” The Examiner

stated that the phrase “at least” in claim 25 was redundant and that it was unclear what limiting effect the phrase “at least” was intended by Applicants with respect to the claim.

Applicants amend claim 25 to delete the phrase “at least” in order to obviate this rejection. This amendment is made for purposes of clarity and for no other reason.

Claim 33, not subject to the rejections under 35 U.S.C. § 102(e) or, in the alternative, under 35 U.S.C. § 103(a), over Imamura et al. ‘433, is now considered allowable.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV. THE REJECTIONS OF CLAIMS 11, 24-32, AND 34-47  
UNDER 35 U.S.C. § 102(e), OR, IN THE ALTERNATIVE,  
UNDER 35 U.S.C. § 103(a) AS OBVIOUS OVER IMAMURA ET AL. ‘433

Claims 11, 24-32, and 34-37 were rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious, over U.S. Patent Application Publication No. 2004/0204433 by Imamura et al. (“Imamura et al. ‘433”).

Imamura et al. ‘433, according to the Office Action, expressly disclosed a lotion containing 5g minoxidil, 10 g 1,3-butylene glycol, 5 g glycerol, 55 g ethanol, citric acid to adjust the pH to 6.0 and sufficient water to make up a total volume of 100 ml. Imamura et al. ‘433, according to the Office Action, also expressly disclosed a composition containing 10-50% by mass of water, 3% by mass or more of minoxidil, 8-30% by mass of polyhydric alcohol, and a pH of 5.5-6.5, wherein the polyhydric alcohol

can be 1,3-butylene glycol, 1,3-butylene glycol and glycerol, or dipropylene glycol and glycerol; the composition can further contain alcohol, a pH adjuster, and vitamin E acetate or glycyrrhetic acid.

Imamura et al. '433 discloses a method for preparing such a composition as follows at paragraph [0012] of the specification:

The hair growth stimulant composition of the present invention is prepared by adding 3% or more of the active component minoxidil and other necessary active compounds and supplementary components to the solvent containing polyhydric alcohol and water, then mixing these components with stirring using a common method. In this instance, it is necessary to adjust the pH in a range of 5.5 to 6.5. If minoxidil is simply added to an aqueous type solvent, the resulting solution is neutral or weakly alkaline. When preparing the high conc. minoxidil preparation using this solution, preparation of crystals occurs readily at a low temperature. On the other hand, if the solution is on the acid side with a pH of 5 or less, minoxidil itself becomes easily decomposable, even though precipitation of crystals does not occur.

The present claims, as amended, recite a minimum concentration of minoxidil or another piperidinopyrimidine derivative of about 6.5%. Although Imamura et al. '433 recites, at paragraph [0012] and elsewhere in the specification, a concentration of minoxidil of "3% or more," there is no example in the specification of any concentration of minoxidil higher than 5%. See Tables 1, 2, 4, and 6 of the specification of Imamura et al. '433; in these tables, the concentration of minoxidil is either 3% or 5%.

Additionally, there is no disclosure in Imamura et al. '433 of any method for preparing minoxidil solutions of such high concentration or any modifications to the simple method for preparing minoxidil solutions disclosed therein.

In addition, the specification of Imamura et al. '433 itself states that, in substantially neutral solutions, minoxidil undergoes precipitation with the formation of crystals. General concepts of kinetics dictate that the rate of precipitate formation, because it involves interactions between two minoxidil molecules or between a minoxidil molecule and an already formed precipitate of minoxidil, proceeds with second-order kinetics; i.e., it occurs at a rate proportional to the square of the minoxidil concentration. This means that precipitate formation occurs far more rapidly when the concentration is increased; a change in minoxidil concentration from 3% to 6% would lead to a fourfold increase in the rate of precipitate formation.

These basic principles of physical chemistry, together with the lack of disclosure or an actual example of any composition containing minoxidil at a concentration greater than 5% in Imamura et al. '433, means that there is no enablement in Imamura et al. '433 for any composition containing minoxidil at a concentration greater than 5%.

This lack of enablement for compositions containing minoxidil at a concentration greater than 5% precludes any possible anticipation of these claims by Imamura et al. '433. To constitute an anticipatory reference under 35 U.S.C. § 102, the prior art must contain an enabling disclosure. Chester v. Miller, 15 U.S.P.Q. 2d 1333, 1336 n.2 (Fed. Cir. 1990); Titanium Metals Corp. v. Banner, 227 U.S.P.Q. 773, 778 (Fed Cir. 1985). In this case, the claims, as amended, require a minoxidil concentration of at least about 6.5%. The absence of any method for preparing such solutions of minoxidil with a minoxidil concentration of at least 6.5% precludes anticipation of these claims.

Therefore, the Examiner is respectfully requested to withdraw this rejection.

Regarding the rejections under 35 U.S.C. § 103(a) in the alternative, the Examiner stated that the prior art discloses products and uses that contain what is stated to be the same exact ingredients or components as that of the claimed invention. However, as extensively described above, the prior art relied upon, in this case Imamura et al. '433, fails to disclose or enable the production of a minoxidil solution with a minoxidil concentration of about 6.5% or greater.

A rejection under 35 U.S.C. § 102(e), or, in the alternative under 35 U.S.C. § 103(a) is only applicable where the prior art reference provides an enabling disclosure. In In re Fitzgerald, 205 U.S.P.Q. 94 (C.C.P.A. 1980), the Court of Customs and Patent Appeals concluded that the reference relied upon clearly provided an enabling disclosure with respect to the cooling rate of the polymer-containing fasteners that was at issue. This clearly distinguishes the factual pattern of In re Fitzgerald from that of the present application.

Similarly, in In re May, 197 U.S.P.Q. 601 (C.C.P.A. 1978), there was a finding by the Court of Customs and Appeals that the composition claims were in fact not obvious because of an unexpected difference in properties. That case, when interpreted properly, supports a finding of non-obviousness because there is no basis in the teachings of Imamura et al. '433 for the preparation of solutions of minoxidil containing at least 6.5% of minoxidil without precipitation of the minoxidil.

Accordingly, the Examiner is respectfully requested to withdraw the rejections under 35 U.S.C. § 102(e) and, in the alternative, under 35 U.S.C. § 103(a), as applied to the amended claims.

## V. CONCLUSION

In conclusion, all claims remaining for consideration particularly point out and distinctly claim that which Applicants regard as their invention. Additionally, these claims are neither anticipated by nor obvious over the references of record, whether these references are considered individually or in combination.

Accordingly, prompt allowance of these claims is respectfully requested.

If any issues remain, the Examiner is respectfully requested to telephone the undersigned at (858) 200-0581.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Michael B. Farber', with a stylized flourish at the end.

Michael B. Farber, Ph.D., Esq.  
Reg. No.: 32,612

Date: April 28, 2008

CATALYST LAW GROUP, APC  
9710 Scranton Road, Suite 170  
San Diego, California 92121  
(858) 450-0099  
(858) 450-9834 (Fax)